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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/986,682	11/09/2001	Keiji Tsusaki	TSUSA1=2B	5800

7590 11/10/2003

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EXAMINER

NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 11/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/986,682

Applicant(s)

Tsusaki et al.

Examiner

Nashaat T. Nashed

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Nov 9, 2001
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above, claim(s) 1-5, 13, and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 08/870,827.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 1
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Claims 1-14 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- | | |
|-----------|--|
| Group I | Claims 1-5, drawn to a polypeptide having β -fructofuranosidase activity, classified in Class 435, subclass 193. |
| Group II | Claims 6-12, drawn to a nucleic acid, vector, and host cell, classified in Class 536, subclass 23.2; Class 435, subclass 252.33. |
| Group III | Claims 13 and 14, drawn to a method for fructofuranosyl transfer, classified in Class 435, subclass 72. |

The inventions are distinct, each from the other because of the following reasons:

The polypeptide of Group I, and the nucleic acid of Group II are independent chemical entities and require different searches in the patent and non-patent literature. Claims drawn to method of making proteins using the recombinant DNA would be placed with the DNA of Group I because, although they have acquired a separate status in the art as shown by their different classification, they do not constitute a burden to search them in addition to the DNA sequences.

Inventions of Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide can be used in other process to make an antibody.

Inventions of Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not disclosed as capable of use together because the nucleic acid of Group II is not used in the method of Group III.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Anne Kornbau on June 9, 2003 a provisional election was made with traverse to prosecute the invention of Group II, claims 6-12. Ms. Kornbau affirmed here oral election with a fax send on June 11, 2003, paper number 7.

Claims 1-5, 13 and 14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claims 6-12 are under consideration.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the application contains nucleic/amino acid sequences which are not identified by a sequence identification number, see for example page 20, first paragraph. Applicants must perfect their compliance with Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claims 6-10 are objected to because the claims are dependent on non-elected claim. Appropriate correction is required. For examination purposes only, the embodiment of claim 1 has been incorporated into claim 6.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 6-9 are rejected under 35 U.S.C. § 101 because the claimed invention is directed toward non-statutory subject matter.

In the absence of the hand of man, naturally occurring proteins and/or nucleic acids are considered non-statutory subject matter. *Diamond v. Chakrabarty*, 206 USPQ 193 (1980). This rejection may be overcome by amending the claims to contain wording such as "An isolated and purified protein or nucleic acid".

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 6-12 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to nucleic acid sequence encoding the polypeptide of SEQ ID NO: 3 including SEQ ID NO's: 4 and 5. The specification does not enable any person skilled in the art to make and use the invention commensurate in scope with these

claims. The claims are broader than the enablement provided by the disclosure with regard to all possible nucleic acid encoding β -fructofuranosidase/ β -fructosyltransferase from any biological or man-made source, said β -fructofuranosidase comprises at least one amino acid residue of 21 and 12 amino acid residues of SEQ ID NO's: 1 and 2, respectively. Factors to be considered in determining whether undue experimentation is required, are summarized *In re Wands* [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claimed invention encompasses any nucleic acid sequence encoding any β -fructofuranosidase/ β -fructosyltransferase comprises one or more amino acid residue of the 21 and 12 amino acid residues of SEQ ID NO's: 1 and 2, respectively, isolated from any biological source. The phrase "in whole or in part" expand the claimed invention to any nucleic acid sequence encoding β -fructofuranosidase/ β -fructosyltransferase activity having any amino acid sequence because "in part" can be only a single amino acid residue. Also, the claimed invention is directed to almost any deletion, insertion, and substitution, and combination thereof mutants. The specification provides guidance and examples in the form of an assay to purify the enzyme from *Bacillus* sp. V230, sequence the N-terminus of the enzyme, construct a probe based on the N-terminus sequence, clone and isolate the nucleic acid sequence of SEQ ID NO: 5 and identify the open reading frame of SEQ ID NO: 4 which encodes the amino acid sequence of SEQ ID NO: 3, and identify the physicochemical properties of the enzyme of SEQ ID NO: 3 (see examples). While molecular biological techniques and genetic manipulation to make the constructs claimed are known in the prior art and the skill of the artisan are well developed, knowledge regarding the biological source of the enzyme, a method to redesign the 455 amino acid residues of the polypeptide of SEQ ID NO: 3 around at least one residue of the 21 and 12 amino acid residues of the polypeptide of SEQ ID NO: 1 and 2, respectively, the amino acid residues which can be deleted, substituted, and inserted in SEQ ID NO: 3 without adverse effects on the catalytic activity of the enzyme, and amino/nucleic acid sequence homology between several species of the claimed invention is lacking. Thus, searching for a nucleic acid sequence encoding β -fructofuranosidase/ β -fructosyltransferase from a biological source and its mutants is well outside the realm of routine experimentation and predictability in the art of success is extremely low. The amount of experimentation to identify a functional β -fructofuranosidase/ β -fructosyltransferase or its mutant is enormous. Since routine experimentation in the art does not include screening vast numbers of genomic, cDNA or man-made DNA libraries where the expectation of obtaining desired enzyme is unpredictable, the Examiner finds that one skilled in the art would require additional guidance, such as information regarding amino/nucleic acid sequence homology among various species of the claimed invention, method of

redesigning the 455 amino acid molecule of SEQ ID NO: 3 while maintaining the desired catalytic activity. Without such a guidance, the experimentation left to those skilled in the art is undue.

Claims 6-12 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following are the reasons for the rejections:

- (a) The phrases "in whole or in part as an amino acid sequence" in claims 6 and 11, and "homologs" in claims 7 and 8 render the claims indefinite because the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. The phrase "in whole or in part as an amino acid sequence" is assumed to mean at least one or more amino acid residues of SEQ ID NO: 1 and 2 which is an indefinite phrase by itself. Thus, the polypeptide of claims 6 and 11 is assumed to be any polypeptide having any sequence and fructofuranosidase/ β -fructosyltransferase activity. Also, the word "homolog" is assumed to mean any nucleic acid encoding polypeptide having fructofuranosidase/ β -fructosyltransferase activity.
- (b) Claims 9, 10, and 12 included in this rejection because they are dependent on a rejected claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-11 are rejected under 35 U.S.C. § 102(b) as being anticipated by Steinmetz *et al.* (IDS, Ref. AR: Mol. Gen. Genet. 1985, 200, 220-228).

Steinmetz *et al.* teach a DNA sequence encoding a levansucrase (E. C. 2.4.1.10), also known as sucrose 6-fructosyltransferase, from *Bacillus subtilis*, and the amino acid sequence encoding said levansucrase, see Figure 3 on page 222. Since any polypeptide with fructosyltransferase has β -fructofuranosidase activity, and the phrase "in part" of SEQ ID NO: 1 and 2 includes at least a single amino acid residue of said sequences, the nucleic acid sequence taught by Steinmetz *et al.* anticipates the claimed nucleic acid of Claims 6 and 9. The word "homologs" in claim 7 and 8 is indefinite as indicated above, and therefore, the claims are assumed to mean any nucleic acid encoding β -fructofuranosidase activity. Thus, claims 7 and 8 are also anticipated by the nucleic acid sequence taught by Steinmetz *et al.* In addition, Steinmetz *et al.* teach the construction

of an expression vector and the transformation of an *coli* host cell to express the enzyme (claims 10-11), see page 223, left column, last paragraph.

Allowable subject matter:

Claims directed to nucleic acid encoding the polypeptide of SEQ ID NO: 3 including SEQ ID NO's: 4 and 5 would be considered favorably.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is (703) 305-6586. The examiner can normally be reached Monday, Tuesday, Thursday, and Friday from 9:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached on (703) 308-3804. The fax phone numbers for this Group are (703) 305-3014 and (703)308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Nashaat T. Nashed, Ph. D.
Primary Examiner